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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,818	12/07/2004	Junzo Tanaka	043070	5270
38834 7590 02/06/2008 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			EXAMINER NAFF, DAVID M	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 02/06/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/516,818

Applicant(s)

TANAKA ET AL.

Examiner

David M. Naff

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 11/9/07.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

An amendment of 11/9/07 amended claims 9, 11 and 13 and added new claim 16.

Claims in the case are 9-16.

5        Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/9/07.

Claims examined on the merits are 9-14 and 16.

10                    ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

15        The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20        Claims 9-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25        Claim 9 is unclear as to how the gradient of calcium phosphate varies. Does the amount of calcium phosphate vary to form the gradient, or does some other characteristic of calcium phosphate vary? The claim should specify the physical property of calcium phosphate that varies to form the gradient.

Claims 11 and 13, line 2, are unclear by reciting "one or more selected" without reciting what constitutes the one or more. It is suggested --- components --- be inserted after "more".

Claim 12 is unclear how the scaffold required differs from the scaffold of claim 11 since claim 12 does not define additional structure or components of the scaffold. Claim 12 merely sets forth an intended function of the scaffold of claim 11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattern et al (6,969,523) or Yannas et al (4,947,840) in view of Sherwood et al (6,454,811).

5 The claims are drawn to a composite material containing a gradient of calcium phosphate in a biodegradable polymeric material selected from collagen, glycosaminoglycan and a composite of collagen and glycosaminoglycan.

Mattern et al (col 1, lines 11-30 and col 3, lines 50-67) and Yannas et al (paragraph bridging cols 1 and 2) disclose scaffolds  
10 formed of cross-linked collagen and glycosaminoglycan.

Sherwood et al disclose (col 4, lines 13-26 and 40-45) forming a gradient of calcium phosphate to provide a composite implantable device for regeneration of bone.

It would have been obvious to provide a gradient of calcium  
15 phosphate in the cross-linked collagen/glycosaminoglycan scaffold of Mattern et al or Yannas et al as suggested by Sherwood et al to make the scaffold suitable for bone regeneration. Components as required by claims 11 and 13 would have been obvious since the components and their functions are known, and it would have been obvious to provide  
20 the components in a scaffold to obtain their expected functions. The scaffold of Mattern et al or Yannas et al is inherently porous as required by claim 16.

*Response to Arguments*

It is granted as urged in the amendment that Mattern et al and Yannas et al do not disclose a gradient of calcium phosphate in the scaffold. However, when Sherwood et al is considered, providing a  
5 gradient of calcium phosphate in the scaffold would have been obvious.

The amendment urges that the method of Sherwood et al dissolves the polymer component and cannot be used to form a gradient in the scaffold of Mattern et al or Yannas et al. However, it would have been expected and obvious that the gradient could be alternatively  
10 formed by merely soaking the scaffold of Mattern et al or Yannas et al in a solution of calcium phosphate so that the calcium phosphate is absorbed into the scaffold. This soaking would result in some variation in the amount calcium phosphate in different parts of the scaffold. For example, the amount of calcium phosphate would be  
15 greater near the exterior surface of the scaffold and gradually become less towards the center of the scaffold. The present claims require no method of forming the gradient that would result in a gradient different than would be obtained when soaking the scaffold in a calcium phosphate solution.

20 *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

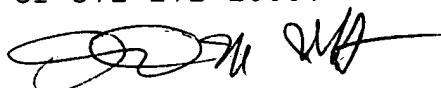
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff  
Primary Examiner  
Art Unit 1657

DMN  
15 2/4/08